Effectiveness of Adjuvanted RSVPreF3 Vaccine in Preventing Major Adverse Cardiovascular Events (MACE), Severe Asthma Exacerbations and Severe Chronic Obstructive Pulmonary Disorder (COPD) Exacerbations Among US Adults Aged 60 Years and Older

Adjuvanted RSVPreF3 vaccination suggests considerable benefit in preventing RSV-related MACE and severe asthma and COPD exacerbations among adults aged ≥60 years

Digital poster
Supplemental data

SCAN ME

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Background

Respiratory syncytial virus (RSV) is a common respiratory infection that typically results in mild, cold-like symptoms; however, **RSV infection can cause severe disease**, especially among adults with certain underlying health conditions,[1,2] and can lead to **major adverse cardiovascular events (MACE)** and **exacerbations of existing medical conditions** such as chronic obstructive pulmonary disease (COPD) and asthma[2,3]

The **effectiveness of adjuvanted RSVPreF3 vaccination against RSV-related hospitalisations** in adults aged ≥60 years has previously been estimated at **83% over one season**[4]

Real-world evidence is needed to evaluate the **vaccine effectiveness (VE) of adjuvanted RSV Prefusion F3 Protein (RSVPreF3) against clinically relevant RSV-related outcomes** among populations at an increased risk for severe RSV disease[4]

Objective

The objective of this analysis was to **assess the VE of adjuvanted RSVPreF3** during the 2023–2024 RSV season among US adults aged ≥60 years in preventing:

- RSV-related and overall MACE, among those with pre-existing CVD
- RSV-related and overall severe COPD exacerbations, among those with pre-existing COPD
- RSV-related and overall severe asthma exacerbations, among those with pre-existing asthma

Variable definitions

- Vaccinated individuals were identified by a medical or pharmacy claim for **adjuvanted RSVPreF3 vaccination during the observation period** (1 August 2023–31 May 2024)
- Outcomes included overall events and RSV-related events. Overall events were identified during any hospitalisation. RSV-related events were identified during RSV-related hospitalisations[a]

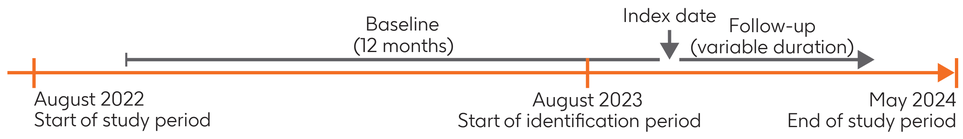
	Populations assessed	Definition (≥1 medical claim); ICD-10-CM codes
MACE	Individuals with baseline CVD	• MI[b] • Ischemic stroke[b] • Heart failure-related hospitalisation[b] • Unstable angina-related hospitalisation[b] • All-cause mortality
Severe COPD exacerbations	Individuals with baseline COPD	• COPD[b]
Severe asthma exacerbations	Individuals with baseline asthma	• Asthma[b]

[a]RSV-related hospitalisation was defined as ≥1 medical claim with RSV diagnosis in an acute inpatient setting; [b]Diagnosis in the primary position on an inpatient medical claim

Methods

Overview

- **CLEAR-VE RSV** (CLaims basEd Assessment of Real-world Vaccine Effectiveness of Adjuvanted RSVPreF3 Vaccination) was a **retrospective cohort study** using administrative claims from Optum Research Database



- **Index date:** adjuvanted RSVPreF3 vaccination date for vaccinated individuals; for unvaccinated individuals, index date was the same date as the vaccinated match[a]
- **Baseline:** 12-month period pre-index date in which baseline characteristics were measured[b]
- **Follow-up** started 14 days after the index date and was used to measure study outcomes[c]

Analysis

- Follow-up began **14 days following the index date,** and censoring occurred at disenrolment, death, receipt of RSV vaccination or end of the analysis period (31 May 2024)
- **Propensity score-based weighting** was used to balance baseline characteristics between the vaccinated and unvaccinated groups[d]
- Hazard ratios comparing the risk of study outcomes between the vaccinated and unvaccinated groups (post-weighting) were estimated using **Cox proportional hazards regression modeling**[e]

VE = (1 – Hazard ratio) × 100%

[a]Vaccinated individuals were exact matched 1:4 to unvaccinated individuals on age (in years), sex, insurance type and US state of residence, without replacement; [b]Continuous enrolment was required during this time period; [c]Follow-up ended at the earliest of the following: death, RSV vaccination, end of continuous enrolment or end of the observation period; [d]Propensity score-based weighting was used to balance age, sex, insurance, HHS region, baseline Quan-Charlson comorbidity score, 20 most common AHRQ Clinical Classification Software comorbidities (overall sample), frailty score, baseline immunocompromised status (including systemic corticosteroids), baseline immunocompromising conditions (HIV, malignancy, other immune conditions), baseline conditions associated with severe RSV disease, baseline tobacco use (any type), baseline vaccination (influenza vaccination, COVID-19 vaccination), baseline healthcare utilisation and baseline all-cause healthcare costs. These variables were included as individual covariates, plus as interaction terms with baseline cardiopulmonary disease (pulmonary or cardiovascular), baseline influenza vaccination, baseline immunocompromised status (including systemic corticosteroids) and baseline diabetes; [e]Hazard ratios were estimated among the weighted population

Results

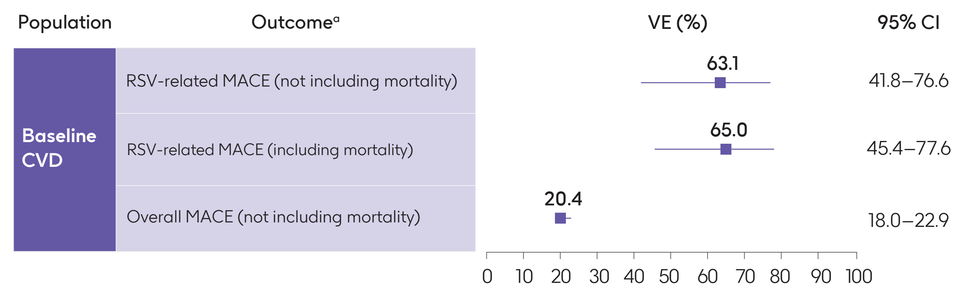
Propensity score-weighted baseline characteristics

	Baseline CVD		Baseline COPD		Baseline asthma	
	Vaccinate N=170,803	**Unvaccinated** N=647,791	**Vaccinate** N=76,209	**Unvaccinated** N=257,365	**Vaccinate** N=53,636	**Unvaccinated** N=142,744
Age, mean (SD)	75.95 (6.87)	75.94 (6.85)	74.90 (6.94)	74.84 (6.88)	73.44 (6.68)	73.30 (6.62)
Female, n (%)	80,966 (47.40)	334,600 (47.86)	42,634 (55.94)	158,038 (55.18)	37,287 (69.52)	134,676 (70.66)
Insurance type, n (%)						
Commercial	7,681 (4.50)	32,080 (4.59)	2,509 (3.29)	9,165 (3.20)	4,300 (8.02)	15,698 (8.24)
Medicare Advantage[a]	163,122 (95.50)	667,097 (95.41)	73,700 (96.71)	277,241 (96.80)	49,336 (91.98)	174,892 (91.76)
Charlson comorbidity score, mean (SD)[5]	2.42 (2.15)	2.42 (2.17)	2.93 (2.09)	2.93 (2.14)	2.44 (1.86)	2.42 (1.88)

Distribution of follow-up time (full cohort): median 5.6 months; maximum: 9.7 months

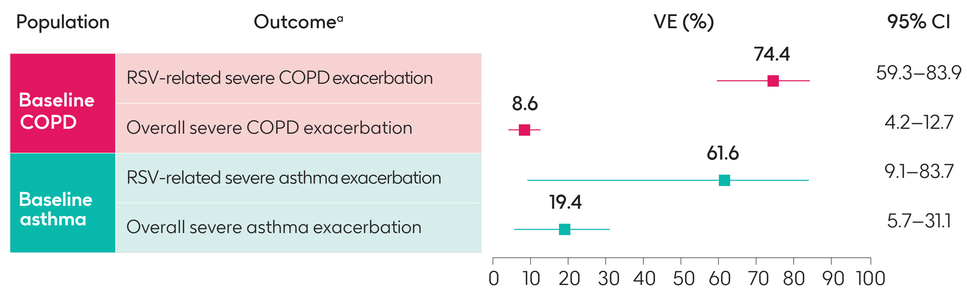
Balance was assessed after weighting in each population to ensure that populations remained similar in their baseline characteristics. [a]Medicare Advantage (also referred to as Medicare Part C) refers to plans provided by private insurance companies

VE against overall and RSV-related MACE



[a]Weighted event counts were 212/699,177 unvaccinated and 21/170,803 vaccinated for RSV-related MACE not including mortality; 234/699,177 unvaccinated and 22/170,803 vaccinated for RSV-related MACE including mortality; 25,194/699,177, and unvaccinated 5,460/170,803 vaccinated for overall MACE not including mortality. Duration of follow-up was variable across individuals

VE against overall and RSV-related severe exacerbations of COPD and asthma



[a]Weighted event counts were 265/286,406 unvaccinated and 20/76,209 vaccinated for RSV-related severe COPD exacerbation; 9,401/286,406 unvaccinated and 2,567/76,209 vaccinated for overall severe COPD exacerbation; 57/190,590 unvaccinated and 7/53,636 vaccinated for RSV-related severe asthma exacerbation; and 895/190,590 unvaccinated and 237/53,636 vaccinated for overall severe asthma exacerbation. Duration of follow-up was variable across individuals

Conclusions

Adjuvanted RSVPreF3 vaccine effectiveness was:
63.1% against RSV-related MACE (excluding mortality)
74.4% against RSV-related severe COPD exacerbations
61.6% against RSV-related severe asthma exacerbations

Findings highlight the **benefits of adjuvanted RSVPreF3 vaccination in individuals at an increased risk for severe RSV disease**

Key limitations included:

- Risk of miscoding/absence of diagnosis codes in administrative claims data
- Results may not generalise to the broader US population
- Without randomisation, and even after adjusted analyses were performed to account for observed differences between the vaccinated and unvaccinated groups, there could still be remaining unmeasured differences that bias VE estimates

Abbreviations

AHRQ, Agency for Healthcare Research and Quality; **CI**, confidence interval; **CLEAR-VE RSV**, CLaims BasEd Assessment of Real-world Vaccine Effectiveness of Adjuvanted RSVPreF3 Vaccination; **COPD**, chronic obstructive pulmonary disease; **COVID-19**, coronavirus disease 2019; **CVD**, cardiovascular disease; **HHS**, Department of Health and Human Services; **HIV**, human immunodeficiency virus; **ICD-10-CM**, International Classification of Disease, 10th Revision, Clinical Modification; **MACE**, major adverse cardiovascular events; **MI**, myocardial infarction; **RSV**, respiratory syncytial virus; **RSVPreF3**, respiratory syncytial virus prefusion F3; **SD**, standard deviation; **US**, United States; **VE**, vaccine effectiveness

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Disclosures

This is an ENCORE of a poster presentation originally presented at RSVVW 2026, 17-20 February 2026. Rome, Italy.
Conflict of interest: CW, DS, EML, EKH, KTN, MJF and SIG are employed by GSK and hold financial equities in GSK. **CW** holds equities in AstraZeneca. **SW** is employed by GSK Australia. **AS, ARB, MGJ, RS and SH** are employees of Optum, and **AS, AB and MGJ** hold financial equities in Optum, which received funding from GSK to conduct this study. **AS** holds financial equities in UnitedHealth Group. **AK and JBL** are employees of RTI Health Solutions, which received funding from GSK to conduct this study.

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